

## **REMARKS**

### **FORMAL MATTERS:**

Claims 58, 59, 60 and 70-72 are pending after entry of the amendments set forth herein.

Claims 61, 62, 63, 65, 66, 67, 68, 69 and 73 are canceled without prejudice.

Claim 72 has been amended to more particularly point out and distinctly claim the invention.

The minor amendment in the final line of claim 72 is formal in nature. The amendment to claim 72 at line 3 is fully supported within previously pending now canceled claim 64. No new matter has been added.

### **PRIORITY**

The Office Action requested specific information relating to the priority claim. Within applicants' response applicants did not intend to specifically indicate that the current application was a continuation or continuation-in-part of the earlier application which issued as U.S. Patent 5,906,202. However, the present application is the non-provisional application of, and as such claims priority to the provisional application Serial No. 60/089,146 filed June 12, 1998, i.e. the present application is the conversion of that provisional application. The U.S. Patent 5,906,202 issued May 25, 1999 which was after the filing of the provisional application 60/089,146 filed June 12, 1998 to which the present application claims priority. Further, the current application names Igor Gonda as a co-inventor and Igor Gonda is named as a co-inventor of the application which resulted in U.S. Patent 5,906,202. Still further, the present application is assigned to Aradigm as is U.S. Patent 5,906,202. The invention disclosed and claimed in the current application was invented under an obligation to assign to Aradigm and the U.S. Patent 5,906,202 was invented under an obligation to assign to Aradigm. Accordingly, the U.S. Patent 5,906,202 is not prior art citable against the present application and under the meaning of 35 U.S.C. §103.

Notwithstanding this position applicants point out that the presently claimed invention is patentable over the disclosure of U.S. Patent 5,906,202. The '202 patent does not disclose the use of protamine sulfate to condense polynucleotides and direct an aerosol containing such polynucleotides to a targeted area of a patient's respiratory tract.

**35 U.S.C. §112, SECOND PARAGRAPH REJECTIONS**

Claims were rejected under 35 U.S.C. §112, second paragraph. The rejection has been overcome by a minor amendment to claim 72 providing an antecedent basis for the phrase “patient’s inhaled volume.” In view of such the rejection has been rendered moot.

**35 U.S.C. §102 REJECTION**

Claims 58-62 and 72 were rejected under 35 U.S.C. §102 as anticipated by Debs. The rejection is traversed as applied and as it might be applied to the presently pending claims.

Applicants point out that the rejection was not applied against dependent claim 73 and the limitations of claim 73 have been included into independent claim 72 thereby rendering the rejection moot.

**35 U.S.C. §103 REJECTIONS**

Claims 58-62 and 72 were rejected under 35 U.S.C. §103 as unpatentable over Debs in view of Jaser et al. The rejection is traversed as applied and as it might be applied to the presently pending claims.

Applicants point out that the rejection was not applied against claim 73 and the limitations of claim 73 are now incorporated into claim 72. Thus, the rejection is believed to have been rendered moot.

Claims 63, 67-69 and 72 were rejected over the combination of Gao et al. in view of Debs and Jaser et al. The rejection is traversed as applied and as it might be applied to the presently pending claims. However, the rejection was not applied against dependent claim 73. The limitations of claim 73 have been incorporated into claim 72. Accordingly, the rejection has been rendered moot.

Claims 64 and 73 were rejected under 35 U.S.C. §103 as unpatentable over Gao et al., Debs, Jaser et al. and further in view of Birnstiel et al. In support of the rejection it was argued that Birnstiel et al. discloses protamine sulfate as a functional equivalent of polylysine and histones for DNA condensation. Accordingly, it was argued that protamine sulfate could be substituted or combined with these in a nucleic acid delivery composition. The rejection is traversed as applied and as it might be applied to the presently pending claims.

First, applicants point out that this combination of references has only been made by utilizing applicants’ own disclosure as a blueprint for combining the references in a particular manner. Thus,

based on this position alone the rejection should be reconsidered and withdrawn. The particular parts of four different references could not be combined in the absence of applicants' teachings.

The primary reference to Debs clearly teaches nebulizer technology which does not allow one to control a patient's inhaled volume as claimed because nebulizers produce a continuous flow of aerosol. The nebulizer of Debs particularly does not allow one to control a patient's inhaled volume of aerosolized formulation and aerosol-free air as claimed in claim 72. Thus, Debs which teaches a nebulizer which produces a constant stream of aerosol is not properly combinable with Jaser which teaches a device which produces pulses of aerosol. In accordance with applicants' invention a particular condensing agent is used to condense the polynucleotide and further the aerodynamic particle size is adjusted and the patient's inhaled volume of aerosolized formulation and aerosol-free air are controlled. This combination of steps allows for the condensation of polynucleotides into a particular size range and the direction of aerosolized particles into a particular area of the lung. The combination of references does not teach such. Further, Birnstiel et al. is clearly not teaching toward any method of targeting an area of a patient's lung.

The remainder of the rejections do not contain rejections of claim 73. In that claim 72 has been amended to incorporate the limitations contained within previously pending now cancelled claim 73 the rejections are believed to have been rendered moot.

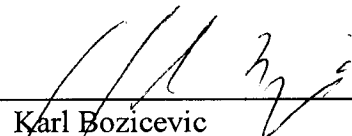
**CONCLUSION**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number AERX-061.

Respectfully submitted,  
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Date: 6/Sept/06

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